OIPE JC143 AUG 08 2005 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

***Gisela** MEIER, **Heinrich** PAJUNK **and Horst** PAJUNK*

Appln. No.: **09/438,759** Group Art Unit: **1641**

Filed: **November 11, 1999** Examiner: **Lam, Ann Y**

Confirmation No.: **9841**

For: **CONTINUOUSLY CONDUCTIVE UNIPOLAR CANNULA FOR ANESTHESIA**

Attorney Docket No.: **2368.098**

Customer number: **000041288**

SUBMISSION OF APPELLANTS' BRIEF ON APPEAL

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Submitted herewith please find an original and two copies of Appellant's Brief on Appeal. A check for the statutory fee of **$250.00** is attached. Authorization is also given to charge or credit any difference or overpayment to Deposit Account No. 16-0877.

Respectfully submitted,

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Bonnie Horst

08-09-05

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BRIEF ON APPEAL

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PARTIES OF INTEREST

The real parties of interest are inventors Gisela Meier, Heinrich Pajunk, and Horst Pajunk.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

This is an appeal to the Board of Patent Appeals and Interferences from the Final Office Action, dated December 15, 2004, finally rejecting claims **27-42**.

STATUS OF AMENDMENTS

It is indicated in the Advisory Action dated April 19, 2005, that the Amendment G filed on March 15, 2005, subsequent to the Final Office Action, has been entered for the purpose of appeal.

SUMMARY OF THE INVENTION

In surgical anesthesia as well as in pain therapy, peripheral nerve blocks, in which small amounts of anesthetic are administered as close as possible to the nerve (perinural), have become an indispensable alternative to general anesthesia.

To precisely localize a nerve, anesthetists use electrical stimulation. A plastic, introducer cannula is placed over a long steel needle, such that only the tip of the steel needle protrudes. As the tip comes close to the nerve, electric current passing through the steel needle and out the tip triggers depolarization of the nerve, manifested, for example, in externally visible muscular contractions of the patient. The needle **must then be withdrawn** from the introducer cannula **to make**

room for introduction of a catheter, through which anesthetic is administered to the nerve.

However, once the conductive needle is withdrawn, it is no longer possible for the anesthetist to confirm whether the remaining introducer cannula tip is in fact still close to the nerve. This is an issue, since the cannula tip may move as the needle is being withdrawn or if the patient inadvertently moves.

Further, the requirement to remove the steel needle prior to introduction of the catheter complicates the procedure.

The closest prior art (Krebs) cited by the Examiner substitutes a solid metal mandrel for the prior art steel needle. However, here also the solid metal mandrel is retracted from the plastic introducer cannula in order to make room for introduction of a catheter (column 3, lines 29-36). Thus, Krebs retains the deficiencies of the prior art. Since the introducer cannula is made of a flexible plastic, after the solid metallic mandrel is removed, the plastic no longer receives guidance. Unintended movements of the patient could cause a change in the position of the tip of the introducer cannula, such that when the catheter is introduced, it will no longer be located in close proximity to the nerve to be blocked. Finally, because the metal mandrel of Krebs is removed, it can no longer be verified by electro-stimulation whether the introducer cannula is near to the nerve.

The present invention overcomes both of the above problems. It makes it possible to **continuously** verify the proximity of the cannula tip to the nerve, and it eliminates one of the steps of the procedure.

In place of **separate** plastic introducer cannula and hollow metal needle, the inventive unipolar cannula is basically an electrically conductive metal cannula tube, having an outer insulating covering leaving only a very small, almost pinpoint

conductive area of the tip free (page 5, lines 15-27). This leads to a higher density of the electric current in the proximate vicinity of the cannula tip. Thus, even minimal current pulses can trigger a depolarization. The small conductive area makes possible an extraordinarily precise placement of the tip compared to conventional introducer cannulas (Page 3, lines 1-8).

In the present invention, the requirement to remove the metal needle from the introducer cannula is thus, eliminated.

When the distal tip of the cannula is in place, then anesthetic can be introduced directly via the cannula tube (using a Luer-lock or needle) (page 3, lines 16-23).

Furthermore, the unipolar cannula itself is used for the guided introduction of the catheter. The catheter tip passes axially or diagonally out through the open distal end of the cannula tube and is brought into the desired position adjacent the nerve to be blocked (page 3, lines 27-30). This also permits direct stimulation of the nerve via the catheter and the exact determination of the catheter tip. Stimulation and injection can also be conducted simultaneously.

Finally, once the catheter is in place, then the unipolar cannula can be pulled out from the catheter from the back, whereby the catheter remains in its position. This less invasive remaining catheter allows the patient more mobility and a quicker recovery. (Page 8, lines 10-13).

The unipolar cannula is extremely versatile. This versatility is achieved using an extremely simple and economical design.

The cannula of the present invention significantly simplifies handling, reduces the number of individual parts, reduces the number of steps, significantly improves the precision of the placement of the catheter, and allows the position of the introducer cannula to be monitored at any time.

ISSUES

1. Whether claims 27, 30-35, 38-39, and 41-42 are properly rejected as obvious over US Patent 4,776,847 (Krebs, et al.), as set forth in the Final Rejection dated December 15, 2004, and maintained in the Advisory Action dated April 19, 2005.

2. Whether claims 28 and 29 are properly rejected as obvious over US Patent 4,776,847 (Krebs, et al.) in view of US Patent No. 4,765,341 (Mower, et al.), as set forth in the Final Rejection dated December 15, 2004, and maintained in the Advisory Action dated April 19, 2005.

3. Whether claims 36, 37, and 40 are properly rejected as obvious over US Patent 4,776,847 (Krebs, et al.) in view of US Patent No. 4,889,529 (Haindl) as set forth in the Final Rejection dated December 15, 2004, and maintained in the Advisory Action dated April 19, 2005.

4. Whether the finality of the Office Action dated, December 15, 2004, was proper.

5. Prosecution history.

GROUPING OF CLAIMS

Claims 27-33, 38-40, and 42 stand and fall together for claiming a cannula having a sharp tip.

Claims 34-37 stand and fall together for claiming a cannula, wherein the distal tip is a facet cut (12).

Claim 41 stands alone, is similar to Claim 27 but including the closed transitional phrase "consisting of" in the preamble.

ARGUMENT

1. Claims 27, 30-35, 38-39, and 41-42 are unobvious over US Patent 4,776,847 (Krebs).

1.1 Examiner's Position

The rejection of December 15, 2004, is maintained, rejecting claims 27, 30-35, 38-39, and 41-42 over US Patent 4,776,847(Krebs).

Regarding Claims 27, 41, and 42

The Examiner indicated that the Krebs reference discloses a cannula comprising a catheter (column 1, line 41); an electrically conductive rigid hollow tube (Mandrel in column 1, line 25 and 43-47) formed by a steel tube (col. 1, line 33) with a sharp tip (col. 1, line 32) with an exit opening (col. 1, line 24) dimensioned for passage of a catheter, a body part (proximal portion of conductive rigid tube) including an inlet opening axially aligned with the cannula tube. The cannula tube has an electrically insulating outer covering (plastic tube, col. 1, line 27) of

the cannula tube, which extend from the body part out to the tip and leaves the tip exposed at least in its distal end (col. 1, lines 29-30). The electrical connector extend through the body part to the outer surface of the cannula tube (col. 1, lines 43-48 and col. 3, lines 19-22). Further, the Examiner indicated that the cannula is unipolar (col. 1, lines 43-51).

1.1 Appellants' Argument

Before going on details to each one of the Examiner's rejection, Appellants submit the following remarks:

Appellants submit that the Examiner is combining two different and mutually excluding approaches in order to reject the present claims. (What was knew before Krebs combined with Krebs teachings).

The Examiner cited the cannula of column 1 of the Krebs reference (hereafter-called cannula 1) to show: the hollow metal tube, catheter, sharp tip, and body part. Cannula 1 corresponds to the **prior art before Krebs.**

In the same rejection, the Examiner indicated that cannula 1 (prior art) includes an electrical connector (column 3, lines 19-22) for electro-stimulation. Appellants note that the cannula on columns 2-3 correspond to the improve cannula according to Krebs (hereinafter called cannula 2).

Cannula 1 comprises a **hollow metal** tube with a **sharp tip.** The hollow, metal tube is inserted through a guiding plastic tube, until the tip of the metal tube extends through the front end of the plastic tube. The hollow metal tube is inserted, until the tip of the hollow metal tube touches the nerve sheath. Then, the nerve sheath is punctured with the metal tube, and the

plastic tube is advanced into the nerve sheath along the hollow metal tube. The metal tube is then **retracted from the plastic tube, and a catheter is introduced** into the nerve sheath. (column 1, lines 31-42)

After puncturing, the resistance of the tissue to the advancing metal tube tip during the advancing of the metal tube is low up to the nerve sheath. As soon as the tip of the metal tube touches the nerve sheath, a perceptibly greater resistance is felt immediately, which decreases at the moment when the nerve sheath is punctured again. This change in resistance to the advancing metal tube is used to check the exact location of the needle. In order to check the exact location of the steel tube, the above cannula attaches a **syringe filled with a saline solution to make the resistance to the advancing metal tube noticeable. (Column 1, lines 43-59). Thus, cannula 1 does not use electric-stimulation.**

Cannula 2 represents an improvement over cannula 1, and comprises a **solid** metallic mandrel (rod) **without a sharp tip.** The mandrel is inserted through a guiding plastic tube, until the tip of the mandrel extends through the front end of the plastic tube (column 4, lines 23-37). A plug-in socket is located on the back of the mandrel. This plug-in socket can receive an electrical plug of an electro-stimulator (column 6, lines 11-20).

Appellants submit that the Examiner is mixing and matching the two different and mutually excluding approaches disclosed by Krebs (old vs. new) in order to provide all the elements of the inventive cannula of the present invention.

Furthermore, Appellants do not understand how the Examiner is adding an electrical connector to cannula 1 if this cannula does not require any electrical connections. Furthermore, Appellants submit that in order to include the electric-stimulation, the design of cannula 1 was modified to obtain cannula 2. The hollow metal tube with sharp tip of cannula 1 was

replaced with a solid mandrel without sharp tip on cannula 2. Syringe filled with saline solution of cannula 1 was replaced with electro-stimulation on cannula 2.

Responding to the Examiner's rejections.

Appellants submit that there are six basic flaws with the Examiner's rejection over the cannulas (cannula 1 and cannula 2) disclosed in the Krebs reference.

(1) The present set of claims requires a **conductive unipolar** cannula for anesthesia. Cannula 1 of the Krebs reference is not an unipolar cannula neither is it a continuously cannula.

An unipolar cannula requires the presence of one electrode. Cannula 1 of the Krebs reference does not include any electrodes or electrical connection. The change in resistance is measured by using the cannula in combination with **a syringe filled with a saline solution.** (Column 1, lines 43-60).

(2) The present set of claims requires that the catheter pass through the electrically conductive rigid hollow tube. Cannula 1 of the Krebs reference teaches the introduction of a catheter into the nerve sheath, **after** the hollow tube is **retracted from the plastic tube** (col. 1, lines 36-42). In addition, cannula 2 also, teaches the introduction of a catheter into the nerve sheath **after** the steel mandrel is retracted from the plastic tube (Column 3, lines 29-40).

Nowhere in cannula 1 and cannula 2 of the Krebs' reference can be found the teaching of using the cannula itself for guiding the catheter, as require by all the claims of the present invention. Thus, Krebs confirms the state of the art over which the present invention improves.

In the present invention, the unipolar cannula itself is use for the guided introduction of the catheter. The requirement to remove the metal needle from the introducer cannula is thus, eliminated.

The cannula of the present invention significantly simplifies handling, reduces the number of individual parts, reduces the number of steps, significantly improves the precision of the placement of the catheter, and allows the position of the introducer cannula to be monitored at any time. This design also permits direct stimulation of the nerve via the catheter and the exact determination of the catheter tip. Stimulation and injection can also be conducted simultaneously.

The unipolar cannula is extremely versatile. This versatility is achieved using an extremely simple and economical design.

(3) The present set of claims requires that the rigid hollow tube be dimensioned for the passage of the catheter. **There is no teaching in Krebs that the catheter is introduced through the hollow metal tube (cannula 1), neither through the steel mandrel (cannula 2). In both cannulas, the catheter is introduced through the plastic tube, after the steel mandrel (cannula 2) or the metal hollow tube (cannula 1) is retracted from the plastic tube. (Col. 1, lines 36-42 and Col. 3, lines 29-36)**

Since Krebs is not concerned with the introduction of the catheter through the hollow metal tube or the solid steel mandrel then, Krebs does not have any technological motivation to modify the dimensions of the hollow metal tube or the steel mandrel to allow the pass of the catheter.

As indicated before, the cannula of the present invention significantly simplifies handling by reducing the number of individual parts, and a significant improvement in the precision

of the introduction of the catheter is achieved. The electrically conducting metallic hollow tube with sharp tip is first used as an electrode for locating the nerve and then, as a guide for injecting an anesthetic into the immediate surroundings of the nerve.

(4) The present set of claims requires a plastic coating fixed on the outer surface of the steel tube. There is no teaching in cannula 1 neither cannula 2 of the Krebs reference of an electrically insulated outer covering **fixed on** (coated) the steel hollow tube. The Examiner is mistaking the plastic tube shown on the reference, which is used as a guide and insulator for the hollow metal tube (cannula 1) and the steel mandrel (cannula 2), as the outer covering that forms **integral** part (fix on) of the hollow metal tube or steel mandrel (cannula 2).

Appellants note that cannula 1 does not required electro-stimulation; thus, there is not any technological motivation to insulate the metal hollow tube. The plastic tube is used as a guider for the metal tube.

Cannula 2 teaches electro-stimulation, but the cannula 2 is not concerned with the introduction of the catheter directly through the **solid** steel mandrel then, Krebs does not have any technological motivation to modify the outer side of the steel mandrel by fix on (coating) an insulating material.

(5) The present set of claims requires the body part to be dimensioned for the passage of the catheter. There is no teaching in Krebs that the catheter is introduced through the hollow metal tube (cannula 1), neither the **solid** steel mandrel (cannula 2). Thus, it can be concluded that the body part attached to the hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2) is not dimensioned for the passage of a catheter.

The catheter is introduced through the plastic tube after

the hollow metal tube (cannula 1) or the **solid** steel mandrel (cannula 2) is removed from the plastic tube. (Col. 1, lines 36-42 and col. 3, lines 29-36).

Since Krebs is not concerned with the introduction of the catheter through the body part, then, Krebs does not have any technological motivation to modify the dimensions of his body part to allow the passage of the catheter.

(6) The present set of claims requires a connector electrically connected to the hollow tube in the area of the body part for electro-stimulation. Appellants note that cannula 1 does not include electro-stimulation. Thus, cannula 1 does not include a connector electrically connected to the body part of the steel tube.

Furthermore, Appellants note that the Examiner indicated on page 3, first paragraph of the Final Office Action of December 15, 2004, that the cannula described in column 1, lines 31-33, (cannula 1) has an electrical connection for electro-stimulation of the nerve tissue.

Appellants submit that nowhere in column 1 of the reference can be found the above-teaching. Cannula 1 does not include electro-stimulation.

Furthermore, the Examiner indicated that cannula 2 shows the connector electrically connected to the body part of the solid steel mandrel.

Appellants do not agree with the Examiner's indication that it would be obvious to a person skilled in the art at the time of cannula 1 was made to add an electrical connector to the body part of the steel tube.

Why adding and electric connector to a cannula that does not

requires electric-stimulation?

Appellants note that adding the connector to the body part of the solid steel mandrel is one of the **improved features of the cannula 2** over cannula 1. Thus, at the time cannula 1 was made, a person skilled in the art would not have had the teaching of the electrical connector of cannula 2.

Furthermore, Appellants note that in order to overcome the deficiencies of cannula 1, Krebs was forced to completely modify cannula 2 by providing a **solid** steel mandrel (cannula 1 shows hollow mandrel) having a tip without cutting edges (Column 2, lines 16-24, and column 4, lines 22-45) (cannula 1 shows a sharp tip) and adding the electrical connector.

Appellants note that the Examiner is combining the teaching of the prior art (cannula 1) at the time the Krebs reference was made with the **improvements** made by Krebs (cannula 2) in order to re-construct the present invention. There being no teaching or suggestion for the combination of these elements; thus, it follows that the prior art cannot render obvious the specific combination of these elements in the same cannula.

The Examiner is using Applicants' disclosure as a blueprint to reconstruct the claimed invention from **isolated pieces of the prior art,** which contravenes the statutory mandate of § 103, which requires judging obviousness at the point in time when the invention was made. *See Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Regarding Claim 30

1.2 Examiner's Position

Krebs does not discloses a ring gap formed between the proximal end of the cannula tube and thereto connected electrically contacting connector and the inner wall of the body

part and wherein the ring gap is filled with plastic. It would have been an obvious matter of design choice to modify the Krebs teaching to include a ring gap filled with plastic since applicant has not disclosed that the ring gap solves any stated problem or is for any particular purpose, and it appears that the Krebs device without a ring gap, would perform equally well as with the ring gap.

1.2 Appellants' Argument

Appellants submit that Claim 30 requires a ring gap formed between the proximal end of the hollow, the connector, and the body part. In addition, Appellants note that the ring gap is filled with a hardening plastic.

Appellants submit that the formation of the ring gap is not an obvious matter of design as suggested by the Examiner. The ring gap is formed by the widening of the body part in the area of the proximal end of the cannula tube. The widening of the body part (conical shape) is required in order to facilitate the introduction of the catheter through the hollow metal tube. Furthermore, Appellants submit that the gap (empty space) is used to allow the entrance of the connector, which will be attached to the hollow tube. The remaining space is filled with a plastic to secure all the components in that area. Thus, the disconnection of the connector is avoided.

Regarding Claims 31 and 32

1.3 Examiner's Position

It would have been obvious to one of ordinary skill in the art to provide a shaft portion disclosed on column 4, line 36 of the Krebs reference (cannula 2) to the cannula disclosed on column 1, lines 31-33 (cannula 1), because it facilitates the delivery of anesthesia or the introduction of a catheter. (Page 4

of the Final Office Action of December 15, 2004).

1.3 Appellants' Argument

Appellants submit that on column 4, line 36 of the Krebs reference there is a teaching that the **PLASTIC TUBE** has a larger diameter in one of its end.

The present set of claims requires that the inlet opening of **the body part of the hollow STEEL TUBE** have a conical shape. The conical shape facilitates the introduction of the catheter **into the steel tube.**

Thus, neither of the hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2) of the Krebs reference that includes the conical inlet.

Furthermore, Appellants note that there is no teaching in Krebs that the catheter is introduced through the **hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2)** or even through the body part. The catheter is introduced through the plastic tube after the **hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2)** is removed from the plastic tube. (Col. 1, lines 36-42 and Col. 3. lines 29-36).

Since Krebs is not concerned with the introduction of the catheter through the body part, then, Krebs does not have any technological motivation to modify the inlet opening of the body part attached to the **hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2),** to facilitate the entrance of the catheter.

Regarding Claim 33 and 38

1.4 Examiner's Position

It would have been obvious to one of ordinary skill in the art, to expose the tip of the rigid hollow tube to a length of

maximally 1 mm since such range is an optimum or workable range. Its has been held that where the general condition of the claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (Pages 4, last paragraph, to page 5, first paragraph, of the Final Office Action of December 15, 2004).

1.4 Appellants' Argument

The arguments set forth regarding Claim 27 are repeated in this section along with the following remarks that concern to the limitation of the exposed area of the distal tip of the hollow tube is maximally 1 mm.

Appellants note the Examiner is correct on the indication that on column 1, lines 23-30, of the Krebs reference there is an indication that the sharp tip of the hollow steel tube **extends through the front end of the tube**. Appellants note that the reference is completely silent regarding the length of the tip that is exposed from the plastic tube.

Furthermore, Appellants note that the sharp tip of the steel tube passes through the plastic tube and is **not coated** into the hollow metal tube (cannula 1) or the solid steel mandrel (cannula 2) as required by the present claims.

In view that the hollow metal tube (cannula 1) and the solid steel mandrel (cannula 2) of the cannulas, according to the Krebs reference, passes through the plastic tube, it is very difficult to control the length of the tip that is exposed beyond the plastic tube.

The present invention requires that the insulating covering leave only a very small, almost pinpoint conductive area of the tip free (page 5, lines 15-27). This leads to a higher density of the electric current in the proximate vicinity of the cannula

tip. Thus, even minimal current pulses can trigger a depolarization. The small conductive area makes possible an extraordinarily precise placement of the tip compared to conventional introducer cannulas (page 3, lines 1-8).

Regarding Claim 34, 35, and 39

1.5 Examiner's Position

It would have been obvious to one of ordinary skill in the art to form the tip of the cannula in column 1, lines 31-33 with an angle of specifically 45° as it is well known.

1.5 Appellants' Argument

The arguments set forth regarding Claim 27 are repeated in this section along with the following remarks that are concern to the limitation of distal tip of the hollow tube is a face cut (Claims 34 and 39), and the face cut is angled to 45° (Claim 35).

Appellants note that cannula 1 requires a sharp tip **of less than 45°.** (Column 1, lines 25-26). Cannula 2 requires a tip **of at least 45°**(column 2, lines 21-22). **Thus, both teachings are mutually excluding one another.**

Modifying cannula 1 by adding the teaching of cannula 2 as suggested by the Examiner is contrary to the teaching of 103.

If a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed. *See In re Fritch*, 972 F.2d at 1265 n.12, 23 U.S.P.Q.2d at 1783 n.12 ("A proposed modification [is] inappropriate for an obviousness inquiry when the modification render[s] the prior art reference inoperable for its intended purpose."); *In re Ratti*, 270 F.2d

810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] as well as a change in the basic principles under which [that reference's] construction was designed to operate").

2. Claims 28 and 29 rejected as obvious over US Patent 4,776,847 (Krebs, et al.)in view of US Patent No. 4,765,341 (Mower, et al.)

Examiner's Position

It would have been obvious to one of ordinary skill in the art to provide a multi-strand connector as taught by Mower, et al. as the connector in the Krebs device in order to provide for flexibility and to endure mechanical stress, which is desirable for lasting use as taught by Mower, et al. (Page 6 of the Final Office Action of December 15, 2004).

Appellants' Argument

Appellants' position regarding the Krebs reference as set forth on Claim 27 are repeated in this section along with the following remarks.

The Mower reference is directed to an **implantable cardiac electrode for defibrillation** (process in which an electronic device sends an electric shock to the heart to stop an extremely rapid, irregular heartbeat, and restore the normal heart rhythm.)

Therefore, this reference cannot give any teaching **for the electrical connection of a cannula for anesthetic.**

Claims 28 and 29 are directed to a special way of contacting the electrically conductive tube of the cannula with the

stimulating wire. Because electrically conductive soldering of steel is difficult, the contact is formed according to claims 28 and 29.

Furthermore, the Krebs reference does not have any technological motivation to include a special way of contacting the electrically conductive tube of the cannula with the stimulating wire. The hollow metal tube (cannula 1) and steel mandrel (cannula 2) pass through the hollow, plastic tube; thus, it will be very difficult to add the connector according to Claim 28 to the hollow metal tube (cannula 1) and steel mandrel (cannula 2), because of the space limitation between the hollow metal tube (cannula 1) or steel mandrel (cannula 2) and the plastic tube.

"In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or; if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986);

3. Claims 36, 37, and 40 are rejected as obvious over US Patent 4,776,847 (Krebs, et al.) in view of US Patent No. 4,889, 529 (Haindl)

Examiner's position

It would have been obvious to form the sharp tip in the Krebs cannula having the configuration as taught by Haindl, such a tip having the advantage of preventing material being punched out of the material to be perforated.

Appellants' Argument

Appellants' position regarding the Krebs reference as set forth on Claim 27 are repeated in this section along with the following remarks.

Appellants note that cannula 1 includes a sharp tip having **lateral facets** (column 1, lines 23-26). The **laterally partially ground facets** at the hollow tip of the steel mandrel produce a sharp tip. (Column 1, lines 60-66).

Cannula 2 specifically teaches the use of a steel mandrel **without sharp tip.**

Appellants agree with the Examiner that the Haindl reference teaches a closed conically arched tip with an exit opening along the side of the hollow steel tube. Appellants submit that the **needle is not used in conjunction with a plastic tube** (guiding tube).

Appellants also note that the Haindl reference discloses a simple needle. The reference is not directed a cannula for electro-stimulation of the nerve sheath.

Appellants submit that hollow metal tube (cannula 1) and steel mandrel (cannula 2) are guided by a plastic tube; thus, the tip of the hollow metal tube (cannula 1) or steel mandrel (cannula 2)needs to be of symmetrical design in order to avoid that the tip scratches the sides of the plastic tube.

Appellants submit that the tip of the Haindl reference is a **conically arched** tip. There is no technological motivation to replace the tip of the device on column 1 of the Krebs reference by the tip showed by Haindl, because the arched shape of the tip

according to Haindl will not allow the smooth pass of the needle through the plastic tube. The arched tip of the needle will hit the walls of the plastic tube, scratching the walls of the tube.

Furthermore, Appellants submit that neither the hollow metal tube (cannula 1), nor the steel mandrel (cannula 2) are used for the delivery of the drug. Thus, a person skilled in the art will not have any motivation to change the shape of the tip of the hollow metal tube (cannula 1) or the steel mandrel (cannula 2) to prevent the material being punched out of the material to be perforated.

In the present invention, the hollow, metal tube itself is used as a guide for the catheter. Thus, the hollow tube does not pass through a plastic guide. The tip of the tube is exposed; thus, the shape of the tip is can be modified according to the physician requirements.

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome, wherein that which only the inventor taught is used against its teacher.

Finally, the references alone or taken with the entire body of patents available to the practitioner, correctly understood, clearly show that those of ordinary skill in this art had no clue of the possibility of the present invention.

The present invention is patentable under the standard established in In re Brouwer, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996). The test of obviousness *vel non* is statutory. It requires that one compare the claim's "subject matter as a whole", with the prior art "to which said subject matter pertains."

Independent Patentability of Claim 41

Claim 41 stands alone, is similar to Claim 27 but including the closed transitional phrase "consisting of" in the preamble.

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited, except for impurities ordinarily associated therewith.").

Appellants' position regarding the Krebs reference as set forth on Claim 27 are repeated in this section along with the following remarks.

Appellants submit that the Krebs reference does not teach a cannula having exclusively the components required by Claim 41.

Thus, Claim 41 is novel and not obvious over the cited prior art.

Appellants cannot understand why the term "consisting of" has not been considered by the Examiner.

4. Whether the finality of the Office Action dated December 15, 2004, was proper.

Applicants respectfully request that the Examiner re-considered the finality of the outstanding Office Action. Reasons are as follows:

1) the Examiner cited new prior art that was not cited before; **and**

2) a second or any subsequent action on the merits in any application or patent involved in examination proceedings **should not be made final** if it includes a rejection, on prior art **not of record**, of any claim amended to include limitations, which should

reasonably have been expected to be claimed.

In the instant case, Claims 27, 34, 38, and 41 (independent claims) were amended by including the limitation "wherein the cannula is unipolar" and deleting from the preamble the limitation "continuously conductive unipolar". **The added limitation should reasonably have been expected to be claimed because one of the main arguments against the cited references was that the cannulas of the references were not unipolar.** Applicants believe that the limitation of the cannula being unipolar was not considered by the Examiner previously because the limitation was in the preamble. (See previous Office Actions).

Thus, the Examiner should be expending the previously presented amendment to the claims.

IN VIEW OF THE ABOVE, THE FINALITY OF THE OFFICE ACTION IS IMPROPER.

5. Prosecution history

The Examiner issued a first Office Action rejecting the claims in view of Prior Art A. A response was filed (Amendment A filed May 6, 2002). A second Office Action was issued. The Examiner withdrawn the previous rejection and issued a **Final Office Action** rejecting the claims over a **complete different set of references** (Prior Art B).

Appellants filed a response after final along with a Request for a telephone Interview (Amendment B filed December 13, 2002). The Examiner refused to enter Amendment B; thus, Appellants filed a Request for Continuous Examination (RCE) on January 13, 2003; thus, Amendment B may be entered and considered by the Examiner.

The Examiner issued a third Office Action withdrawing the previous rejection and rejecting the claims in view of a **complete**

different set of reference (Prior Art C). Appellants filed a response (Amendment C filed May 20, 2003), the Examiner withdrew the previous rejection and issued a fourth Office Action (Second Final **Office Action in the case)** rejecting the claims over a complete different set of references (prior art D).

CONCLUSION

The present invention overcomes the problems of the prior art because in place of **separate** plastic introducer plastic tube and hollow metal tube, the inventive unipolar cannula is basically an electrically conductive metal cannula tube, having an outer insulating covering leaving only a very small, almost pinpoint conductive area of the tip free. Thus, the electrically conducting metallic hollow tube and sharp tip is first used as an electrode for locating the nerve and then, as a guide for injecting an anesthetic into the immediate surroundings of the nerve. The use of other parts, such as plastic tube can be omitted entirely when using the cannula according to this invention, so that handling is significantly simpler. At the same time, the guidance of the catheter to be placed is done directly over the puncture needle with which earlier the immediate surroundings of the nerve to be blocked was found with extremely high precision in the known manner using a stimulating current.

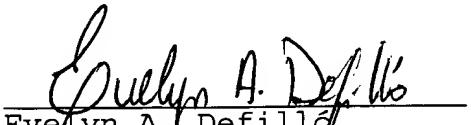
The cannula of the present invention significantly simplifies handling, reduces the number of individual parts, reduces the number of steps, significantly improves the precision of the placement of the catheter, and allows the position of the introducer cannula to be monitored at any time.

No prior art reference provides suggestion for the present invention.

Accordingly, reversal of the Examiner is respectfully

requested. All claims are believed to be in allowable condition.

Respectfully submitted,



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APPENDIX

CLAIMS ON APPEAL

27. A cannula for anesthesia comprising:

a flexible catheter,

an electrically conductive rigid hollow tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a sharp tip (14) and an exit opening in the area of the sharp tip (14) dimensioned for passage of the catheter,

a body part (18) provided at the proximal end of the hollow tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the hollow tube (10) adapted for guiding the catheter for introduction into the proximal end of the hollow tube (10), and

a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said hollow tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the hollow tube (10)

wherein the cannula is unipolar.

28. A cannula according to Claim 27, wherein an electrical connection is formed between the electrical connector and hollow tube by an electrical contact pressed against the circumference of the hollow tube (10), to which a contact ~~a~~ wire (24) of a multi-strand connector (26) is soldered.

29. A cannula according to Claim 28, wherein the wire (24) lies axially parallel against the hollow tube (10), and the multi-strand conductor (26) runs radially through the body part (18) towards the outside.

30. A cannula according to Claim 27, wherein the proximal end of the hollow tube (10) is provided co-axially in the body part (18), wherein a ring gap is formed between (a) the proximal end of the hollow tube (10) and the thereto connected electrically contacting connector (22, 24) and (b) an inner wall of the body part (18), and wherein said ring gap is filled with plastic (30).

31. A cannula according to Claim 27, wherein the inlet opening of the body part (18) decreases in diameter to form an inlet funnel oriented co-axially towards the proximal end of the hollow tube (10).

32. A cannula according to Claim 27, wherein the proximal end of

the body part (18) is a Luer-lock connection (34).

33. A cannula according to Claim 27, wherein the electrically exposed end area (16) of the distal tip (14) of the hollow tube (10) has a length of maximally 1mm.

34. A cannula for anesthesia comprising:

a flexible catheter;

an electrically conductive rigid hollow tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a tip (14) and an exit opening in the area of the tip (14) dimensioned for passage of the catheter,

a body part (18) provided at the proximal end of the hollow tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the ~~a~~ hollow tube (10) adapted for guiding the catheter for introduction into the proximal end of the ~~a~~ hollow tube (10), and

a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said hollow tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the hollow tube (10);

wherein the distal tip (14) of the cannula tube (10) is a facet cut (12)

wherein the cannula is unipolar.

35. A cannula according to Claim 34, wherein the facet cut (12) is angled at an angle of approximately 45° to the axis of the hollow tube (10).

36. A cannula according to Claim 27, wherein the distal tip (14) of the hollow tube (10) is formed as a closed conically arched tip with an exit opening (44) provided along the side of the hollow tube proximally behind this tip.

37. A cannula according to Claim 36, wherein a ramp (46) is formed on the inside of the distal end of the hollow tube (10), adapted to guide a catheter toward the exit opening on the side of the cannula.

38. A cannula for anesthesia comprising:

a flexible catheter;

a steel electrically conductive hollow tube (10) including a proximal end and a distal end, the distal end including a sharp

tip (14) and an exit opening (12, 44) in the area of the tip (14) dimensioned for passage of the catheter,

a body part (18) provided at the proximal end of the hollow tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the hollow tube (10) for guiding a catheter for introduction into the proximal end of the hollow tube (10), and

a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said hollow tube (10) has an electrically insulated outer covering extending from the body part (18) out to the tip (14) and which leaves about 1mm of the tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the hollow tube (10)

wherein the cannula is unipolar.

39. A cannula as in claim 38, wherein said hollow tube tip is a facet cut tip.

40. A cannula as in claim 38, wherein said hollow tube tip is a Sprotte tip.

41. A cannula for anesthesia consisting of:

a flexible catheter;

an electrically conductive rigid hollow tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a sharp tip (14) and an exit opening in the area of the sharp tip (14) dimensioned for passage of the catheter,

a body part (18) provided at the proximal end of the hollow tube (10), the body part (18) including an inlet opening (32, 34) axially aligned with the hollow tube (10) adapted for guiding the catheter for introduction into the proximal end of the hollow tube (10), and

a connector (22, 24, 26) electrically connected to the hollow tube (10) in the area of the cannula body part (18) for transmission of electro-stimulation,

wherein said hollow tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the hollow tube (10)

wherein the cannula is unipolar.

42. A cannula for anesthesia comprising:

a catheter;

an electrically conductive rigid hollow tube (10) formed by a steel tube including a proximal end and a distal end, the distal end including a sharp tip (14) and an exit opening in the area of the sharp tip (14) dimensioned for passage of the catheter,

a body part (18) provided at the proximal end of the hollow tube (10), the body part (18) including a funnel shaped inlet opening (32, 34) axially aligned with the hollow tube (10) to insert the catheter into the proximal end of the hollow tube (10), and

a connector (22, 24, 26) for transmission of electro stimulation, wherein the connector passes through the body part and makes electrical contact with the hollow tube (10) in the area of the body part (18) ,

wherein said hollow tube (10) has an electrically insulated outer covering extending from the body part (18) out to the sharp tip (14) and which leaves the sharp tip (14) exposed at least in its distal end area (16), and

wherein said electrical connector (24, 26) extends through the body part (18) to the outer surface of the hollow tube (10)

wherein the cannula is unipolar.